

Institutional Review Board

rights and welfare of human research subjects

Investigator Requirements for Retaining Research Data






Regulations require each investigator to retain research data not only while the research is being conducted but also after the research is completed. How long do you have to keep the records after the completion of the research? Unfortunately, there are several different regulations each of which has different requirements. As a result researchers must comply with the longest applicable standard according to current institutional policies.

OHRP Requirements: 45 CFR 46 requires research records to be retained for at least 3 years after the completion of the research.

HIPAA Requirements: Any research that involved collecting identifiable health information is subject to HIPAA requirements. As a result records must be retained for a minimum of 6 years after each subject signed an authorization.

FDA Requirements: Any research that involved drugs, devices, or biologics being tested in humans must have records retained for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified. *Please note – this length of time can be much greater than 2 years. You should receive written confirmation from the sponsor and/or FDA granting permission to destroy the records.* (21CFR312.62.c)

VA Requirements: At present records for any research that involves the VA must be retained indefinitely per VA federal regulatory requirements. This could be subject to change if federal regulators establish a national policy setting a shorter period for retention. Please contact the VA Research for additional information at: (352) 376-1611, extension 6069.

UF Requirements – patents: Any research data used to support a patent through  must be retained for the life of the patent in accordance with  Intellectual Property Policy   please direct any questions to the Office of Technology and Licensing 

Sponsor Requirements – contract: If your study is sponsored you must insure that you comply with any terms for record retention detailed in the contract with the sponsor. For example, a sponsor may require you to retain your research related documents for 20 years. Prior to agreeing to a contract that specifies how long records will be maintained you should insure you will receive adequate funding to pay for the storage.

Questions of data validity: if there are questions or allegations about the validity of the data or appropriate conduct of the research, you must retain all of the original research data until such questions or allegations have been completely resolved.

In Summary:

Research Records must be maintained a minimum of three years after the research is completed and the study closed with the IRB.

Records may need to be kept longer if other requirements apply.

Researchers must comply with the longest applicable standard as described above.

